

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
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THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8421

Bartle, C.J.

March 10, 2010

Gail Palomarez ("Ms. Palomarez" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,<sup>1</sup> seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").<sup>2</sup>

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 (continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In March, 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Charles M. Rasmussen, M.D., F.A.C.C. Based on an echocardiogram dated April 25, 2001, Dr. Rasmussen attested in Part II of Ms. Palomarez's Green Form that she suffered from severe mitral regurgitation, the presence of ACC/AHA<sup>3</sup> Class I indications for surgery to repair or replace the mitral valve that was not performed, that valvular repair/replacement surgery was medically

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2. (...continued)

describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

3. "ACC/AHA" means the American College of Cardiology and the American Heart Association.

indicated, but that the patient declined to consent to surgery.<sup>4</sup> In the Green Form, Dr. Rasmussen included a handwritten explanation stating: "[s]urgery has been discussed. The decision for surgery has been deferred because of dramatic improvement in both symptoms as well as echo findings with medical management. The patient remains a candidate for surgery in the future." Based on such findings, claimant would be entitled to Matrix A-1, Level III<sup>5</sup> benefits in the amount of \$855,717.<sup>6</sup>

— In the report of claimant's echocardiogram, Eileen Frelier, M.D., the reviewing cardiologist, noted that "[t]he

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4. Dr. Rasmussen also attested that Ms. Palomarez suffered from pulmonary hypertension secondary to moderate or greater mitral regurgitation, an abnormal left ventricular dimension, an abnormal left atrial dimension, a reduced ejection fraction less than 30%, and New York Heart Association Functional Class II symptoms. These conditions, however, are not at issue in this claim.

5. In Part I of her Green Form, Ms. Palomarez requested Matrix Benefits at Level IV. Upon review of claimant's Green Form and supporting materials, the Trust determined, and claimant did not dispute, that Ms. Palomarez alleged conditions consistent only with a claim for Level III benefits.

6. Under the Settlement Agreement, a claimant is entitled to Level III benefits if the he or she has: "[s]evere regurgitation and the presence of ACC/AHA Class I indications for surgery to repair or replace the aortic and/or mitral valve(s) and a statement from the attending Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist supported by medical records regarding the recommendations made to the patient concerning valvular surgery, with the reason why the surgery is not being performed." Settlement Agreement § IV.B.2.c.(3)(b).

mitral valve is thickened, but moves normally."7 Dr. Rasmussen, however, attested in claimant's Green Form that Ms. Palomarez did not suffer from mitral annular calcification ("MAC"). In further explanation of his answer on the Green Form regrading MAC, Dr. Rasmussen included a handwritten note stating: "[c]linically insignificant echogenicity noted on mitral annulus." Under the Settlement Agreement, the presence of MAC requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)ii)d). As the Trust does not contest Ms. Palomarez's entitlement to Level III benefits, the only issue before us is whether claimant is entitled to payment on Matrix A-1 or Matrix B-1.

In November, 2003, the Trust forwarded the claim for review by Waleed N. Irani, M.D., one of its auditing cardiologists. In audit, Dr. Irani concluded that there was no reasonable medical basis for Dr. Rasmussen's finding that claimant did not have MAC. In support of this conclusion, Dr. Irani explained that there was "MILD Mitral Annular Calcification PRESENT."

Based on the auditing cardiologist's diagnosis that claimant had MAC, the Trust issued a post-audit determination that Ms. Palomarez was entitled only to Matrix B-1, Level III

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7. Claimant's medical records also include reports written by Dr. Rasmussen for subsequent echocardiograms performed on May 14, 2001 and November 29, 2001, in which Dr. Rasmussen observed, respectively, that "[t]he mitral valve appears to be anatomically normal" and "[t]here is calcification of the mitral annulus."

benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.<sup>8</sup> In contest, claimant argued that she should prevail because, although MAC is present, her attesting physician concluded that it "is of no clinical significance" and "does not account for [claimant's] severe mitral regurgitation." As stated in an affidavit of claimant's attesting physician:

In my opinion, Gail Palomarez'[s] very small amount of mitral annular calcification that is seen on the echocardiogram does not account for her regurgitation. I believe that the mitral annular calcification that she has is clinically insignificant.

Accordingly, in claimant's view, "[m]itral annular calcification that is not causing the severe regurgitation should not be utilized to substantially reduce the benefits of a claimant."

The Trust then issued a final post-audit determination, again determining that Ms. Palomarez was entitled only to Matrix B-1, Level III benefits. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to

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8. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Palomarez's claim.

show cause why Ms. Palomarez's claim should be paid. On January 20, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 4381 (Jan. 20, 2005).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on May 31, 2005. The Show Cause Record is now before the court for final determination. See Audit Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that she did not have MAC. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Palomarez argues that "[t]he only issue in this matter is whether minimal or clinically insignificant mitral annular calcification is an appropriate Reduction Factor that can be relied upon to make this claim a

Matrix B-1 Level III claim as opposed to a Matrix A-1 Level III."9 Claimant avers that the Settlement Agreement should not be interpreted to reduce the amount of benefits based on the presence of MAC that has "no clinical effect on the valvular dysfunction being compensated for ...." (emphasis in original). Claimant further contends that other reduction factors for mitral valve claims "require present effect on the valvular dysfunction in order to be considered a reduction factor." (emphasis in original).

In response, the Trust argues that, under the Settlement Agreement, any amount of MAC reduces a mitral valve claim to Matrix B-1, regardless of whether the MAC was significant enough to cause regurgitation.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, we reject Ms. Palomarez's position that the level of MAC must be clinically significant to justify a reduction in benefits. The Settlement Agreement specifically provides that a claimant will receive reduced Matrix Benefits for a mitral valve claim if he or she is

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9. Claimant asserts that applying the Settlement Agreement as written "discriminates against older people since minimal amounts of mitral annular calcification are commonly found in the older population." Age, however, was considered by the parties in determining the factors that would reduce the amount of Matrix Benefits due to a claimant. See, e.g., Settlement Agreement § IV.B.2.d.(2)(c)i)c) (reduction factor of aortic sclerosis applied to individuals  $\geq$  sixty (60) years of age). Further, as the Settlement Agreement does not provide an age restriction for MAC, we will decline claimant's request to draft such a restriction into the Settlement Agreement.

diagnosed by echocardiogram with MAC. See Settlement Agreement § IV.B.2.d.(2)(c)ii)d). Although claimant relies on Dr. Rasmussen's opinion that her MAC was not clinically significant, the Settlement Agreement provides that the presence of MAC, regardless of level, requires the payment of reduced Matrix Benefits. Unlike some of the other factors that reduce a claim to Matrix B-1, any presence of MAC, regardless of the amount, places the claim on Matrix B-1. Compare Settlement Agreement § IV.B.2.d.(2)(c)ii)d) with Settlement Agreement § IV.B.2.d.(2)(c)i)d) ("Aortic root dilatation > 5.0 cm").

Moreover, Ms. Palomarez's reliance upon Dr. Rasmussen's opinion that the presence of MAC was not the medical cause of her severe mitral regurgitation is misplaced. Causation is not at issue in resolving Ms. Palomarez's claim for Matrix Benefits. Rather, claimant is required to show that she meets the objective criteria set forth in the Settlement Agreement. As we previously concluded:

Class members do not have to demonstrate that their injuries were caused by ingestion of Pondimin and Redux in order to recover Matrix Compensation Benefits. Rather, the Matrices represent an objective system of compensation whereby claimants need only prove that they meet objective criteria to determine which matrix is applicable, which matrix level they qualify for and the age at which the qualification occurred ....

PTO No. 1415 at 51 (Aug. 28, 2000). In addition, we noted that:

... [I]ndividual issues relating to causation, injury and damage also disappear because the settlement's objective criteria



provide for an objective scheme of compensation.

Id. at 97. If claimants are not required to demonstrate causation, the converse also is true; namely, in applying the terms of the Settlement Agreement, the Trust does not need to establish that a reduction factor caused the regurgitation or valve replacement at issue. The Settlement Agreement clearly and unequivocally requires a claim to be reduced to Matrix B-1 if any amount of MAC is present. We must apply the Settlement Agreement as written. Accordingly, Dr. Rasmussen's opinion that claimant's MAC was not the cause of her severe mitral regurgitation is irrelevant.

Finally, we disagree with claimant that the reduction factors set forth in the Settlement Agreement, when viewed collectively, "require present effect on the valvular dysfunction in order to be considered ... reduction factor[s]." (emphasis in original). To the contrary, each reduction factor is separately identified, the application of which is determined by reference to the specific definition for each reduction factor. As the definition of MAC in the Settlement Agreement clearly applies, Ms. Palomarez's claim must be reduced to Matrix B-1.

For the foregoing reasons, we conclude that claimant has not met her burden in proving that there is a reasonable medical basis for finding that she did not have MAC. Therefore, we will affirm the Trust's denial of Ms. Palomarez's claim for Matrix A-1 benefits.